



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/331,631	06/21/99	MANNERS	CULLN23.001A

HM12/0314
KNOBBE MARTENS OLSON & BEAR
620 NEWPORT CENTER DRIVE
SIXTEENTH FLOOR
NEWPORT BEACH CA 92660-8016

EXAMINER	
ROBINSON, H	
ART UNIT	PAPER NUMBER
1653	10

DATE MAILED: 03/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/331,631

Applicant(s)
Manners et al.

Examiner
Hope Robinson

Group Art Unit
1653



☒ Responsive to communication(s) filed on Dec 28, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3, 11, 13, 16-23, 30, 34 and 41 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 11, 13, 16-23, 30, 34, and 41 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on Jun 21, 1999 is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's response to the Office Action mailed June 8, 2000 in Paper No. 8 on December 12, 2000 is acknowledged. It is noted that applicant is requesting a rejoinder of claims 12, 14-15, 31-33, 36-37 and 39-40 upon allowance of the pending claims. It is also noted that applicant has amended the non-elected claims and has presented them for examination. However, at this time no claims are presently allowable. It further noted that applicant has submitted a new sequence listing.

2. Claims 1, 2, 11, 13, 16, 18 and 19 have been amended. Claims 4-10, 24-29, 35 and 38 have been canceled. Claims 1-3, 11, 13, 16-23, 30, 34 and 41 are pending.

3. The objections to the Specification and Abstract have been withdrawn. The rejection under 35 U.S.C. 103(a) has been withdrawn. The following grounds of rejection are or remain applicable :

Drawings

4. The drawings filed on June 21, 1999 remain objected to because Figure 13 and 15 are missing a portion of the Western Blot. See also the Draftsperson's Review Comments.

Correction is required.

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5. The amendment filed December 12, 2000 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claim 16 has been amended to read that the designing is done "using a computer modeling program". The specification provides no indication of such a step in the claimed method.

Applicant is required to cancel the new matter in the reply to this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 16 and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 16 and the dependent claims hereto introduced new matter into the claims because it is recited in item (a) "obtaining from a known sequence or designing, using a computer modeling program an amino acid sequence which forms a helix-turn-helix structure".

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No support was found for this in the instant specification. The specification does not describe a method step that indicates that “designing is done via a computer modeling program”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3, 11, 13, 16-23, 30, 34 and 41 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1 what is “relative” spacing. Based on the formula C3XC(10-12)X-C3XC, the spacing can be C-XXX-C-XXXXXXXXXXXX-C-XXX-C or C-XXX-C-XXXXXXXXXXXX-C-XXX-C or C-XXX-C-XXXXXXXXXXXX-C-XXX-C as set forth in SEQ ID Nos 37-39, yet the claims recite “comprising a relative cysteine spacing” which is open to other arrangements besides the ones above (see also claim 18). The dependent claims are included in this rejection.

Claim 3 needs spacing between SEQ ID No: 1 and SEQ ID No: 5.

Claim 13 lacks antecedent basis for “said microbes”, the claim should recite “by reducing the number of microbes”.

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Claim 16 remain indefinite because (1) “obtaining or designing” require steps which are unrecited; (2) it is not apparent which residues would or would not be selected to only achieve “substantially” the same distribution of positive charges, and (3) if item (a) and (b) are already done, what is the necessity of item (c) of Claim 16 else there is a missing step (d) of isolating the protein. The dependent claims are also included in this rejection.

Claim 17 is indefinite as to “tyrosine/phenylalanine”, what does the slash mark mean, “or” or “and/or”.

Claim 20 is indefinite for the recitation of “substantially the same antimicrobial activity”, what is considered to be “substantially the same”.

Claim 21 remains indefinite because in the sequence listing recites residues 29 to 94 for SEQ ID NO: 23 which only has 33 residues based on the raw sequence listing also note that residues 31-85 is recited as SEQ ID No: 24 which should be SEQ ID No: 25.

Claim 22 remains indefinite because SEQ ID NO: 27 is recited as containing 17 residues and the sequence disclosure indicates that there are 16 residues for this sequence. The dependent claim is also included in this rejection.

Claim 34 is indefinite since (a) the claim does not indicate the effect of controlling; (b) that the time and conditions of application are effective to produce the effect indicated in (a).

Applicant's arguments filed on December 12, 2000 in Paper No. 8 have been fully considered but were not persuasive. Note that the objection to the Drawings remain because

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applicant did not address this in the response. Note also that the amendments to the claims has introduced new matter, thus the rejection over claim 16 under 35 U.S.C. 112, second paragraph remains. The response on page 5 asserts that the rejection of claim 22 is obviated by the amended sequence listing. However, the rejection remains the claim has not been amended to reflect the changed sequence, although applicant indicated that a new sequence listing was provided.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claim 1 is rejected under 35 U.S.C. 102 (a) as being anticipated by Tatar et al. (EP 093652, November 9, 1996).

Tatar disclose peptides used to vaccinate against *E. coli* enterotoxins. In addition, Tatar disclose the sequence contained in SEQ ID No: 39 with the formula C3XC12XC3XC wherein X is any amino acid and C is cysteine, with a 100% sequence identity. Therefore, the limitation of the claim is met by this reference (see sequence alignment and pages 1-2 of the reference).

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7. Claim 1 is rejected under 35 U.S.C. 102 (a) as being anticipated by Voermanr (WO 96/13585, May 9, 1996).

Voerman disclose protease inhibitors obtainable from leeches. Voerman also disclose a medicament and pharmaceutical preparations. Voerman further disclose the sequence contained in SEQ ID No: 37 with a 100% sequence identity where the sequence is C3XC10XC3XC, wherein X is any amino acid and C is cysteine (see the alignment and abstract). Therefore, the limitation of the claim is met by this reference (see sequence alignment and pages 1-2 of the reference).

Conclusion

8. No claims are presently allowable.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

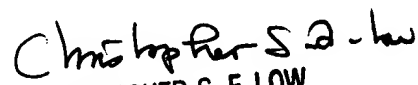
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Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600